

### **REMARKS**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

#### **A. Claim Amendments**

By the present communication, claim 70 is amended and new claims 98-104 are added. Claims 1-69, 73-76, 79-85, 92 and 94-96 were previously canceled.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

No new matter is added by this amendment. The amendment to claim 70 and new claims 98-104 are supported by the Examples and the claims as originally filed.

After amending the claims as set forth above, claims 70-72, 77-78, 86-91, 93, 97, and 98-104 are now pending in this application. Entry of the amendment is respectfully requested.

#### **B. Response to Claim Rejections under 35 USC Section 112 (Enablement)**

Claims 70-72, 77-78, 86-91, 93, and 97 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled.

Specifically, the Action alleges that the specification “does not reasonably provide enablement for a method of treating heart failure associated with loss of cardiac muscle contractility ... wherein the S16E PLB gene is administered via any and all means to *any and all target sites*.” (Office Action at page 2, emphasis added).

Without acquiescing in the substantive basis of the rejection, Applicants have amended the claims to recite that the phospholamban gene encoding protein having an S16E mutation is administered to a target site; i.e., cardiac muscle. Thus, the S16E PLB gene is not administered “to any and all target sites.” Rather, the S16E PLB gene is administered to cardiac muscle where expression of the encoded protein can increase SERCA2-mediated cardiac muscle contractility.

Moreover, Applicants respectfully submit that the Examiner’s concern that the claims encompass administration “via any and all means” has been rendered moot by the amendment to claim 70. Indeed, the skilled artisan would recognize that not all of the routes of administration set forth in the Office Action e.g., topical, intra-dermal, oral, nasal, etc. (Office Action at page 3) would be suitable for achieving administration to cardiac muscle. For similar reasons, Applicants submit that this rejection does not apply to newly added claim 98, and claims 99-104 depending therefrom, which recites that that the phospholamban gene encoding a protein having an S16E mutation is administered to cardiac muscle by intracoronary injection.

Applicants submit that the amended claims are in line with the scope of enablement identified in the Office Action, and are therefore in condition for allowance. Accordingly, reconsideration and withdrawal of the enablement rejection is respectfully requested.

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Chien et al.  
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Filed: September 11, 2001  
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**CONCLUSION**

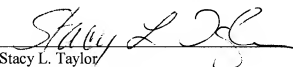
Applicant believes that the present application is now in condition for allowance.  
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge \$405.00 for the Request for Continued Examination fee to Deposit Account No. 07-1896. No other fees are believed to be due in connection with the filing of this paper. However, the Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment, to Deposit Account No. 07-1896.

Respectfully submitted,

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